TESTIMONY OF

THE AMERICAN UROLOGICAL ASSOCIATION

TO

THE SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

COMMITTEE ON COMMERCE

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H.R. 15

THE MEDICARE PREVENTIVE BENEFIT IMPROVEMENT ACT OF 1997

PRESENTED BY

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Mr. Chairman and Members of the Subcommittee:

My name is James B. Regan, M.D., and I am Assistant Professor of Surgery in the Division of Urology at Georgetown University Medical Center, here in Washington, D.C. I am pleased to have the opportunity to express the enthusiastic support of the 9200 members of AUA for H.R. 15, the Medicare Preventive Benefit Improvement Act of 1997. This legislation would add significant new preventive and screening benefits to Medicare, including coverage for early detection of prostate cancer. If enacted, male Medicare beneficiaries would finally have coverage of the prostatic specific antigen (PSA) blood test and digital rectal examinations (DRE) for early detection of this disease. In my testimony today, I would like to explain to the Subcommittee why this is an important benefit and dispel some of the confusion and controversy that surrounds this issue.

AUA's members want to express their appreciation to you, Mr. Chairman, for your leadership in introducing this important bill. We also want to thank the other Members of this Subcommittee and the House of Representatives who have joined you in cosponsoring H.R. 15. The bipartisan support for this measure gives us great hope that favorable action can occur this year. We are certainly prepared to work with you to secure passage.

Mr. Chairman, prostate cancer is a killer. The American Cancer Society (ACS) estimates that in 1997 334,500 new cases will be diagnosed and 41,800 men will die from this disease. Prostate cancer is now the second leading cause of cancer death in men, exceeded only by lung cancer. In 1997, prostate cancer will be the most commonly diagnosed cancer among men, excluding skin cancers. These statistics are on the rise, and there has been a significant increase in the number of prostate cancer cases over the past 35 years.

Prostate cancer incidence rates are 66% higher for African-American men than for white men. In fact, African-American men have the highest rate of prostate cancer in

the world. Because of this fact, any African-American man over the age of 40 must be considered at high risk for this disease.

Unfortunately, there is often a perception among the general population and within some medical circles that prostate cancer is not a serious disease, one that often needs no treatment, and only simple surveillance or observation is required to manage it. Nothing can be further from the truth.

While prostate cancer is a disease found more frequently in older men, and some who have the disease diagnosed later in life would not be candidates for treatment, it also occurs in younger men whose life is dramatically shortened by this disease. Furthermore, the disease in its terminal stages causes untold pain and suffering due to bone metastasis and major organ involvement.

Prostate cancer closely parallels breast cancer in age of onset, incidence, five year survival rates and death rate. The techniques for early detection of breast cancer are generally well accepted, but are not significantly more accurate or more effective than the tools available today for the early detection of prostate cancer. With the discovery of PSA and with the development of transrectal ultrasonic-controlled prostatic biopsies, the ability of American urologists to diagnose this disease at an early stage has been enormously enhanced. For the first time, urologists are capable of making a diagnosis when the disease is in a curable state--still confined in the capsule of the prostate. Like most cancers, early diagnosis improves treatment outcome and increases treatment choices.

This is a far cry from just a few years ago. Prior to the use of PSA, most patients diagnosed with prostate cancer were diagnosed well beyond the time when urologists could offer them a curative therapy. They were condemned to the slow deterioration that accompanies advanced prostate cancer. If they were lucky, another cause of

death delivered them from the pain of advanced disease.

There is now evidence that early detection is beginning to have an impact. An important indicator is the stage at which prostate cancer is diagnosed. Prior to the use of PSA, only 30-40% of men were diagnosed with early stage cancer. Among individuals getting annual PSA tests, early stage disease is the diagnosis 70-85% of the time. The opportunity for cure is much higher among men with early stage disease. Some early studies suggest that efforts at early diagnosis and effective therapy may be paying dividends. In the United States the mortality rate from prostate cancer fell 6.3% between 1971-1990 and 1991-1995. This decline was greatest in men under the age of 75 where it fell 7.4%. If these trends continue, it may be possible to conclude that efforts at early detection and treatment have resulted in decreased death rates.

The American Urological Association and the American Cancer Society have comparable guidelines for early detection of prostate cancer. A copy of AUA's statement is attached.
Note that I speak about "early detection", not "screening". When urologists talk about early detection of prostate cancer, they are referring to finding the disease early in a population already at risk for developing this cancer. Because the onset of prostate cancer is age related, we urge all men over 50 to be tested annually. These men are in a high risk category by virtue of that anniversary.

Other men at risk are African-American men, and I have cited the disturbing statistics about the incidence of prostate cancer in that population. Any African-American male over age 40 is at risk and should be tested annually.

The other major risk category is familial. We know that men whose fathers, uncles, grandfathers and brothers have had prostate cancer are themselves at greater risk. Men with a family history should be tested every year after age 40.

The prostate cancers that will kill over 40,000 men this year all began as small, microscopic tumors confined to the prostate. Life threatening prostate cancers do not suddenly appear one day as a massive tumor that has spread throughout the body. If these cancers are detected early and the entire prostate is removed, the men will be free of cancer. Studies dating back nearly 20 years show that men with organ-confined prostate cancer who underwent surgery have a survival rate equivalent to that of men of similar age who never had prostate cancer.

It is clear that if we are to prevent death from prostate cancer, it is necessary for men to be diagnosed with prostate cancer when it is at an early organ confined state and for curative treatment to be initiated at that time. To ensure that life threatening cancers are discovered at a curable stage requires annual prostate checkups that include a digital rectal exam and a prostate specific antigen (PSA) test.

We cannot wait until a man develops symptoms to give these tests. When prostate cancer is at a curable stage, there are no symptoms. When a prostate cancer causes symptoms, such as blood in the urine, pain or sudden onset of difficulty with urination, it is no longer curable.

AUA recommends that both the DRE and PSA be performed. Each test finds different cancers, although PSA can detect twice as many cancers as DRE, and many more of these cancers are at a curable stage than occurs with DRE. It really is important that both tests be covered, and H.R. 15 achieves this goal in its legislative language. Passage of this bill will also assure that any remaining financial hurdles that might prevent a male Medicare beneficiary from seeking these services are eliminated.

Once a cancer is discovered, then it is up to the individual and the physician, working together as a team, to decide on the preferred management. Depending on the tumor and the man's age, health and his preference, one of four treatment options may be

chosen: radiation therapy, surgery called "radical prostatectomy", hormonal therapy, or no therapy. There are benefits and risks to each choice, as well as quality of life issues to consider. Prostate cancer is no different from other cancers in this regard. There are often treatment options for the physician and the patient to decide upon, and there are frequently risks to any of those choices. The present state of cancer therapy is not easy, but the outcomes can be excellent. Just because the choices are sometimes difficult, we should not deny men the opportunity to learn about their disease early. AUA has developed a guideline on the management of prostate cancer for use by physicians and their patients. This guideline can clarify some of the choices that must be made when a diagnosis of prostate cancer is confirmed.

All of us would like more certainty in early diagnosis and treatment, but the uncertainties that exist should not be a bar to enacting this legislation. Only by discovering prostate cancer early, can physicians give their patients a true choice in treatments. Passage of H.R. 15 would assure that male Medicare beneficiaries retain this choice in their lives.

As you consider this legislation, you will need to examine the costs to Medicare if the bill were to be enacted. AUA urges you to weigh carefully the costs of enactment against the savings that will stem from avoidance of costly palliative therapies and the loss of productive life. We can think of few better investments for this Congress than passage of this bill.

In summary, the rationale for early detection of prostate cancer is simple:

1) prostate cancer kills;
2) no cure exists for advanced prostate cancer;
3) all prostate cancers begin as organ confined tumors; and,
4) patients with organ confined cancers who are managed with curative therapy (such as radical prostatectomy) have survival rates similar to those of the general population.

Mr. Chairman, this concludes my statement. Our members are ready to work with you and the Members of the Subcommittee to pass this important legislation. I would be happy to answer any questions you or the Subcommittee Members may have.